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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/815,356 | 03/31/2004 | Mark S. Zeiner | END5008USC1P2 | 8274 |
| 27777 7590 03/11/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON | | | EXAMINER | |
| | | | YABUT, DIANE D | |
| ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | L | ART UNIT | PAPER NUMBER |
| | | | 3734 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 03/11/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|-------------------|--|--|--|--|
| Office Action Comments | 10/815,356 | ZEINER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | DIANE YABUT | 3734 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>07 No</u> | ovember 2007 | | | | | |
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| ,— | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| _ | | | | | | |
| 4) Claim(s) <u>1-6, 8-11, 17, 19 and 23-33</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) <u>1-6,8-11,17,19 and 23-33</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | alestian requirement | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ acce | epted or b) \square objected to by the E | Examiner. | | | | |
| Applicant may not request that any objection to the o | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Tupor Notice of Dransperson's Patent Drawing Review (PTO-946) Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | |

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DETAILED ACTION

This action is in response to applicant's amendment received on 11/07/2007.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1, 6, 8-9, 17, 23-27, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber** (U.S. Patent No. **5,385,552**).

Claims 1, 6, 8-9, 17, 23-27, 29-32: Haber discloses a trocar 2 with a hollow cannula 32 having a distal end and proximal end and a valve housing 58 attached to the proximal end of the cannula, wherein the proximal end has a wall attached thereto having an aperture therethrough, and an instrument seal assembly 122 disposed within said housing comprising a first substantially rigid ring 132, and a second substantially rigid ring 134 and a plurality of layered elastomeric members, or four separate semicircular seal segments 126, compressed therebetween, each having a circumference of 180 degrees, and arranged circumferentially about an aperture in an alternating over and under pattern in a non-planar shape (the elastomeric members also have a non-planar shape prior to being assembled together), and circumscribing an aperture in an interwoven pattern and cooperating to seal against objects positioned

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within the aperture, and each seal segment has a starting edge facing in the same circumferential direction and an ending edge facing in the opposite circumferential direction wherein the starting edge of each seal segment overlaps and is positioned on top of the ending edge of the adjacent seal segment, and the seal segments cooperate to seal against objects or instruments positioned within the aperture (Figures 2 and 5A).

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Haber discloses each seal segment having a circumference of 180 degrees but does not expressly disclose the segments having a circumference greater than 180 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made for the seal segments to have a circumference greater than 180 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

3. Claims 2-3, 10-11, 19, 28, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber** (U.S. Patent No. **5,385,552**), as applied to Claims 1, 9-10, 17 and 25 above, and further in view of **Honkanen** (U.S. Patent No. **4,655,752**).

Claims 2 and 10: Haber discloses the claimed device except for the plurality of layered elastomeric members forming a conical shape.

Honkanen teaches a cannula with a conically-shaped seal **55** (Figure 4).

Honkanen teaches that the conical shape assists in the formation of a tight seal about an instrument being inserted into the cannula since fluid pressure will cause the conical seal member to collapse into the instrument and cause it to adhere more securely

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thereto (col. 4, lines 53-58). It would have been obvious to one of ordinary skill in the art at the time of invention to provide conically-shaped elastomeric members, as taught by Honkanen, to Haber in order to facilitate a secure adhesion to the inserted instrument.

Claims 3, 11, and 19: Haber discloses the claimed device except for the elastomeric members comprising a proximal flange portion and an inwardly extending portion extending distally therefrom, wherein said proximal flange portions are disposed between and are abutting against said rings.

Honkanen teaches a proximal flange portion **56** and an inwardly extending portion **58**, wherein said proximal flange portions which would be disposed between and are abutting against the rings in the device of Haber (Figure 2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a proximal flange portion and an inwardly extending portion, as taught by Honkanen, to Haber since it was known in the art that seals with such portions are more securely mounted to the valve housing and more efficiently seal instruments that move through the valve.

Claims 28 and 33: Haber discloses the claimed device except for the seal further providing zero-closure seal.

Honkanen teaches the seal further providing zero-closure (Figure 5) and it would have been obvious to one of ordinary skill in the art to modify Haber by providing zero-closure, as taught by Honkanen, in order to form a tighter seal that would allow a snug fit about the instrument and to prevent fluid from escaping out the top end of the cannula (col. 4, lines 45-52).

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4. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Haber** (U.S. Patent No. **5,385,552**) in view of **Hart** (U.S. Patent No. **5,385,553**)

<u>Claim 4</u>: Haber discloses the claimed device except for the seal assembly having an outer perimeter which is attached to a flotation means.

Hart teaches the seal assembly having an outer perimeter which is attached to a flotation means **39** that allows for movement of the septum orifice to an off-axis position without deformation (Figure 12, col. 2, lines 6-18 and col. 10, lines 41-63). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Haber in providing a flotation means being attached to the outer perimeter of the seal assembly, as taught by Hart, in order to prevent deformation of the septum orifice.

Claim 5: Haber discloses the claimed device except for the seal assembly including a

Hart teaches seal assembly including a plurality of protectors that comprises outer leaves **105**, **107** and inner leaves **125**, **127** disposed proximal to said elastomeric seal (Figures 9-10, col. 6, lines 48-68). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a plurality of protectors proximal to elastomeric seal, as taught by Hart, to Haber in order to shield the sealing members from the pushing force of the instruments.

plurality of protectors disposed proximal to said elastomeric seal.

Response to Arguments

5. Applicant's arguments filed 11/07/2007 have been fully considered but they are not persuasive.

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The applicant generally argues that Haber does not teach that the seal assembly 122 cooperates to seal against objects positioned within the aperture, and actually teaches the very opposite since the proximal seal 122 is intended to seal the trocar when an object is not positioned in the path. Although this is true, it is evident in Figure 3A of Haber that when an object (obturator barrel 14) is in the path, the sealing assembly (between rigid rings 132 and 134) engages the object and seals or prevents the movement of fluid in some degree, and therefore the device of Haber reads on the limitation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/ Examiner, Art Unit 3734 /Todd E Manahan/ Supervisory Patent Examiner, Art Unit 3731